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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/083,462      | 02/27/2002  | Vincent Fischetti    |                     | 5777             |

7590 11/05/2002  
Jonathan E. Grant  
Suite 210  
2120 L Street, N.W.  
Washington, DC 20037

EXAMINER

GOLLAMUDI, SHARMILA S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 11/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/083,462

Applicant(s)

FISCHETTI ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Amendment B received on August 5, 2002 is acknowledged. Claims 27-38 are included in the prosecution of this application. Claims 15-26 are cancelled.

### ***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection necessitated by amendments.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 27-30 and 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyauchi (4900730) in view of Liu et al (5374545).**

Miyauchi teaches a rectal suppository containing lysozyme chloride for the gastrointestinal tract (Note abstract and example 37). The reference teaches the use of EDTA for increasing the absorption of the medicine (col. 5, lines 4-7). The reference teaches the pH range for the composition (note examples).

Miyauchi et al do not teach the target killing of specific bacteria.

Liu et al teach enzymes that are capable of depolymerizing bacterial cell walls to prevent the growth of target microorganisms such as E.coli, Salmonella, and Campylobacter (col. 1, lines 21-30). Liu teaches the lytic enzyme functions at a pH of 7 (col. 2, line 65). The enzymes are taught for use in the healthcare industry and its

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incorporation into solid enzyme preparations where the enzyme is lyophilized (col. 1, line 66 and col. 7, line 15). Liu discloses that foodborne infection is caused by the ingestion of viable bacteria, which then grow and establish themselves in the host, resulting in illness (col. 5, lines 55-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate Liu's lytic enzymes in Miyauchi's suppository base since Liu teaches lytic enzymes with target killing of bacteria which cause food poisoning.

In the absence of showing the criticality of using citrate-phosphate buffer versus phosphate buffer, it is deemed obvious to one of ordinary skill in the art to use either since the prior art teaches the instant pH using a phosphate buffer.

**Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyauchi (4900730) in view of Liu et al (5374545) in further view of Goldstein et al (5861295).**

As set forth above, the references teach compositions containing lysozymes.

The references do not teach the use of instant reducing reagent.

Goldstein et al teach the method of producing thermostable enzymes. The reference teaches a filtration buffer solution containing EDTA and the dithiothreitol. The reference discloses that it is known to one of ordinary skill in the art to substitute buffer solutions as long as they have the equivalent effect (col. 8, lines 35-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use dithiothreitol and EDTA since Goldstein et al teach buffer solutions such as this are known to one of ordinary skill in the art.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-308-0196.

SSG

*[Handwritten signature]*

November 1, 2002

*[Handwritten signature of Michael G. Hartley]*

MICHAEL G. HARTLEY  
PRIMARY EXAMINER